differently. When analysts report the results of study, both total and incremental budget impact should be presented for each year of the time horizon. Sensitivity analysis was emphasized in order to identify the uncertainty within the analytic framework. The guidelines suggested that the discounting is unnecessary and encourage model validation except those of Poland. **CONCLUSIONS:** This review discovered that Canada, Ireland, Poland, and ISPOR BIA guidelines were consistent in basic analytic framework, but details were depended on payer perspective and regional specificity. This study is expected to help to develop Korean BIA guidelines.

**PHP12**

**A COMPARISON OF NEW DRUGS APPROVED BY THE EMA AND THE FDA IN 2006-2011**

Alshehri N[1], Seoane-Vazquez E[2], Rodriguez-Monguio R[3]
[1]*Massachusetts College of Pharmacy and Health Sciences, Boston, MA, USA,* [2]*MCPHS University, Boston, MA, USA,* [3]*University of Massachusetts, Amherst, MA, USA*

**OBJECTIVES:** The European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have different regulatory systems for the review and approval of new drugs. This study reviewed and compared the characteristics of priority review new pharmaceuticals (i.e. new molecular entities -NME- and new therapeutic biologics -BLA-) approved by EMA and the FDA in the period 2006-2011. **METHODS:** Data were extracted from the FDA and EMA websites. Dates of application and approval and orphan status information were extracted from the FDA approval letters and the EMA public assessment reports. Descriptive statistics were used to compare the approval processes and characteristics of both systems; t-test was used to assess differences in average review time. Significant level was set at 0.05. **RESULTS:** A total of 47 drugs (34 NME and 13 BLA) were approved by both regulatory agencies in the study period. BLAs were submitted to the FDA 22±166 days earlier (median=10 days) and approved by the FDA 211±145 days earlier (median=168 days) than the EMEA. NMEs were submitted to the EMA 229±832 days earlier (median=33) and approved by the EMA 97±884 days earlier (median=173 days) than the FDA. The average review time was statistically significantly lower (p<0.001) for the FDA 258±200 days (median=184 days) than for EMA 406±96 (median=407 days). The number of products with orphan designation at the time of the first approval was higher in the FDA (n=20) than in the EMA (n=15). EMA granted orphan designation at the time of approval to two products that did not have orphan designation in the US. **CONCLUSIONS:** There are significant differences in the time elapsed between the filing and the approval of priority review products in the US and EU. Orphan designation also varied between the two regulatory systems. Harmonization of the regulatory systems could facilitate timely approval of essential pharmaceuticals.

**PHP13**

**AN EVALUATION OF THE ASSOCIATION BETWEEN AN FDA SUICIDALITY WARNING AND ANTIEPILEPTIC MEDICATION USE IN A STATE MEDICAID PROGRAM**

Mittal M[1], Harrison DL[1], Thompson DM[1], Miller MJ[2], Farmer KC[1], Ng YT[1]
[1]*University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA,* [2]*University of Oklahoma Health Sciences Center, Tulsa, OK, USA*

**OBJECTIVES:** In January 2008, the Food and Drug Administration (FDA) communicated concerns and later in May 2009, issued a warning about an increased risk of suicidality related to all antiepileptic drugs (AEDs). The purpose of this study is to evaluate the association between an FDA suicidality warning and AED use among Oklahoma Medicaid enrollees diagnosed with epilepsy and/or psychiatric disorder(s). **METHODS:** A longitudinal interrupted design was conducted to study Oklahoma Medicaid claims data from January 2006 through December 2009. A total of 13,126 individuals met the study criteria: diagnosis with epilepsy and/or psychiatric disorder(s) and filling of at least one AED prescription. A segmented logistic regression model compared the level and trend in the log odds of AED use among three time periods: a baseline period of 25 months (Jan. 2006 - Jan. 2008) before the FDA warning; the 16 months (Feb. 2008-May 2009) during the FDA warning; and the 7 months (June 2009-Dec. 2009) after the FDA warning. Generalized estimation equations (GEE) were used to estimate trends in AED utilization while adjusting for several covariates. **RESULTS:** There was a statistical increase in the trend, expressed as a monthly change in log odds of AED use, before the FDA warning period (p<0.0001). However, this trend decreased by 34% (99% CI: 10.2% to 57.6%, p=0.0002) during the FDA warning period when compared to the baseline trend. This decrease in trend did not remain significant after the FDA warning period (p=0.2957). Compared with the baseline level of AED utilization before the FDA warning period, the log odds of AED utilization level also decreased by 22% (99% CI: 1.9% 42.2%, p=0.0048) after the FDA warning period. **CONCLUSIONS:** The FDA suicidality warning was associated with a reduction in overall AED use among this population.

**PHP14**

**THE IMPACT OF KOREAN PROSPECTIVE DRUG UTILIZATION REVIEW PROGRAM ON THE RATE OF DRUG-DRUG INTERACTIONS**

Kim DS, Jeon HR, Kang HA, Park CM
*Health Insurance Review & Assessment Service, Seoul, South Korea*

**OBJECTIVES:** Since December 2010, online computerized prospective DUR(pDUR) has been implemented in Korea. pDUR involves the review of each prescription before the medication is dispensed to the individual patient. The pDUR is performed electronically by Health Insurance Review & Assessment Service (HIRA), which is a Korean governmental agency, and then HIRA provides medical institutions and pharmacies with information that can be helpful to them in preventing potential drug problems such as drug/drug interactions or ingredient duplication. The aim of this study was to assess the impact of the Korean pDUR implementation on the rate of drug-drug interactions (DDIs) using claims data of HIRA. **METHODS:** A before-after comparison of the prevalence of DDIs was conducted, using HIRA administrative claims data from medical institutions from January 2010 to December 2011. In addition, a paired t-test was applied to examine the difference between the pre- and post-pDUR. The analysis unit was the prescription issued and main outcome measures were the rates of DDIs within- (control group) or between- physician encounters. **RESULTS:** The mean DDIs rates (pre-test and post-test) within patient visits were 0.29‰ and 0.22‰, respectively. The mean rates of DDIs between visits were 0.94‰ (before) and 0.80‰ (after). As a result of the t-test, we found that DDIs rate between encounters decreased significantly (t=3.04, p=0.0026) after the implementation of pDUR, whereas there is no significant reduction within encounters (t=1.15, p=0.2518). With respect to the prevalence of DDIs between drug groups, the most dramatic reduction was occurred between HMG CoA reductase inhibitors and anti-fungal agents. **CONCLUSIONS:** It seems effective that giving a direct feedback to prescribers by a prospective DUR. Further research is needed to assess the impact of DUR to final outcomes such as hospitalization.

**PHP15**

**"SAFE AND EFFECTIVE" VERSUS "REASONABLE AND NECESSARY": IS THE DECK STACKED AGAINST DEVICES?**

Mordin M[1], Hogue S[2], Barrows S[1], Van Amerongen D[3]
[1]*RTI Health Solutions, Ann Arbor, MI, USA,* [2]*RTI-Health Solutions, Research Triangle Park, NC, USA,* [3]*Humana, Cincinnati, OH, USA*

**OBJECTIVES:** US Food and Drug Administration (FDA) approval does not necessarily equate with coverage by the Centers for Medicare and Medicaid Services (CMS) or private payers for a device or a drug. The FDA is charged with determining the safety and efficacy of medical products. In contrast, payers are primarily concerned with whether medical products are reasonable and necessary. As health care costs continue to rise, manufacturers face increasing pressures to justify product prices and provide rationale to payers to support favorable funding decisions. Our objective was to review coverage decisions for devices and reasons for noncoverage to determine whether payers are expecting more pharmaceutical-like evidence. **METHODS:** We reviewed Washington State Health Technology Assessment (HTA) decisions for therapeutics from 2007 through 2012. Reasons for noncoverage were classified as lack of clinical efficacy or other. **RESULTS:** We identified 22 therapeutic HTA reviews, of which 11 included some level of noncoverage determination for the product or procedure. The reason for noncoverage was stated as a perceived lack of clinical efficacy evidence. For example, a 2008 decision against implantable infusion pumps for the treatment of chronic noncancer pain was based partly on the fact that "[t]he only kind of evidence about whether implantable infusion pumps are effective for patients with chronic noncancer pain comes from uncontrolled case series." Such statements demonstrate the disparity between FDA approval of devices and payer expectations for efficacy evidence to support coverage decisions. Payer evidence requirements for medical devices continue to move closer to those historically associated with pharmaceuticals. **CONCLUSIONS:** No roadmap exists for determination of reasonable and necessary levels of evidence for device-coverage decisions. FDA and payer evidence requirements are not aligned. Moving forward, evidence-generation efforts for devices will, in most cases, have to exceed FDA requirements in order for payer evidence needs to be met.

**PHP16**

**REVIEWING AND REFINING THE CONCEPTUAL FRAMEWORK FOR THE CURRENT DRUG DEVELOPMENT PARADIGM (CDDP)**

Rosenberg E[1], Pistollato M[2], Deverka PA[1], Mestre-Ferrandiz J[2]
[1]*Center for Medical Technology Policy, Baltimore, MD, USA,* [2]*Office of Health Economics, London, UK*

**OBJECTIVES:** To examine how five global pharmaceutical companies are currently developing comparative effectiveness research (CER) and relative effectiveness (RE) evidence. **METHODS:** We followed two parallel steps. First, a targeted literature review was performed. Second, a semi-structured interview program was conducted with 19 senior key informants (KI) across the five companies. After analyzing the interview results using systematic content review, we merged these findings with the literature review to extrapolate the final study results. **RESULTS:** We found a clear recognition of the growing importance of CER/RE within the industry, although the KIs differed regarding whether this was a disruptive change or simply an extension of traditional outcomes research efforts. Most viewed the payer/HTA community as the biggest driver of CER/RE evidence needs, rather than patients or clinicians. Nearly all KIs stated that their organizations already incorporate CER/RE criteria into their current drug development paradigm (CDDP), but differed in the timing (phase of development), degree of investment, whether CER/RE considerations influenced go/no-go decisions and type of product. Barriers to adaptation of the CDDP included historic prioritization of regulatory approval; concerns about increased study costs and complexity; heterogeneity of stakeholder evidence requirements; and difficulty integrating across departments. Facilitators of change included increasing CER/RE expectations of payers/HTA bodies and having senior management serve as an internal CER/RE champion. Most interviewees believed that CER/RE would play a greater role in drug development by 2020, particularly driven by payer/HTA demands for evidence of value. **CONCLUSIONS:** Our interviews revealed that there has been a spectrum of response to the perceived need for CER/RE data that involves altering the CDDP in a variety of important ways to include primarily the information needs of payers and HTA bodies. These changes to the CDDP are projected to grow